REMARKS

Claims 1-43 were pending. Claims 1-7 and 12 were under consideration. Claims 1-4 have been amended. Claims 12 and 36-43 are canceled; Claims 8-11 and 13-35 are withdrawn from consideration. No new matter is added. Support for the amending language of Claims 1-4 may be found in the specification at paragraph [112], which describes epitopes and antibodies; and paragraph [004] which describes specific amino acid residues of interest.

Applicants respectfully request reconsideration of the rejections.

Claims 1-7 and 12 have been rejected under 35 U.S.C. 112, first paragraph as allegedly failing to comply with the written description requirement. The Office Action states that the genus of MFPs include a vast number of peptides that vary in length from 8-315 amino acids, and that the genus includes peptides which have no structural similarity to other peptides within the genus.

Applicants respectfully submit that the presently claimed invention meets the requirements of 35 U.S.C. 112, first paragraph. Claims 1-4 have been amended. In particular, independent Claim 1 has been amended to recite a composition comprising an antibody that specifically binds to an epitope within a specific region of the laminin 5 alpha 3 polypeptide, which region has been specifically shown by Applicants to be involved in migration facilitation. Applicants respectfully submit that such a genus of antibodies is supported by the written description of the instant application.

With respect to the adequacy of disclosure, Applicants wish to point the Examiner to the Interim Training Materials provided by the Patent Office for certain fact patterns relating to whether a claimed invention meets the requirements for written description. In particular, Applicants note Example 16, which, for convenience, is reproduced below:

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in

the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced. The claim is directed to any antibody which is capable of binding to antigen X. A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.

Applicants respectfully submit that the facts of the present claims fall within the fact pattern set forth in the training materials. The present claims are drawn to a genus of a spectrum of antibodies binding to a well-defined region of a polypeptide that has been characterized as to its amino acid sequence. As with the above example, antibodies having specific binding properties are essential to the claims as presently amended.

As stated in the training materials, "the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced". One of skill in the art would therefore recognize that applicant was in possession of the claimed invention. In view of the above amendments and remarks, withdrawal of the rejection is requested.

Claims 1-7 and 12 have been rejected under 35 U.S.C. 102(b) as anticipated by Carter *et al.*, U.S. Patent no. 6,120,991. Applicants respectfully submit that the presently claimed invention is not anticipated by the cited art.

As described above, Claims 1-4 have been amended to recite an antibody that binds to an epitope within specific regions, i.e. the G4/5 region, of the alpha 3 polypeptide. The antibodies described in the prior art do not bind to this region, and thus are outside of the scope of the present claims.

Carter et al. disclose antibodies that bind to the alpha 3 chain of epiligrin, which protein generally corresponds to the laminin 5 alpha 3 polypeptide. These antibodies bound to epitopes in the E170 band of the epiligrin complex (P1E1) or to the E36 band (P1H8) as stated in Example 5 of the '991 patent:

> Monoclonal antibodies P1E1 and P1H8 selected (above, Example 2) for specific binding to HFK-ECM and not to HFF-ECM, e.g., P1E1, bound to ^{35}S-methionine radiolabeled epiligrin complex in HFK-conditioned media (prepared as in Example 3, above) and the immunoprecipitate formed by adding a second antibody (i.e., rabbit or goat anti-murine IgG and IgM H and L chain sera) with carrier proteins (e.g., diluted murine sera containing murine IgG and IgM) contained E200, E170,E145,E135 and E36. (FIG. 2, lanes marked "P1E1").
>
> P1E1 did not bind to any of the epithelial ligand glycoproteins when they had been reduced and subjected to SDS-PAGE under reducing conditions, suggesting that the P1E1 antigenic epitope may be conformational and denatured in these treatments.
>
> The glycoproteins immunoprecipitated by P1E1 include relatively greater amounts of E170 than E135, E145, or E200. These findings indicate: a) that E170 may contain the P1E1-reactive antigenic epitope in the epiligrin complex; and b) that E170 may also exist in HFK-conditioned media as a glycoprotein independent of the epiligrin complex.
>
> P1H8, while binding to HFK-ECM and soluble epiligrin complex in HFK-conditioned media, did not bind to the endogenous epiligrin complex in HFK cells unless the plasma membrane was permeabilized to allow entry of antibodies into the cytoplasm. P1H8 immunoprecipitated E36 from HFK-conditioned media in amounts relatively greater than E200, E170, E145 or E135 indicating: a) that E36 contains the P1H8 antigenic epitope of the epiligrin glycoprotein complex; and b) that E36 is also present in HFK-conditioned media as a glycoprotein independent of the epithelial ligand complex.

E170, the focus of the Carter patent, is not the full laminin-5/epiligrin α3 chain, but rather is a processed α3 chain, which lacks the G4/5 domain. The unprocessed α3 chain migrates as a larger band, at approximately 200 kD, which band was not characterized by Carter *et al.* Therefore neither the patent nor the antibody have any connection with the G4/5 domain.

In view of the above amendments and remarks, Applicants respectfully submit that the presently claimed invention is novel in view of the cited art. Withdrawal of the rejection is requested.

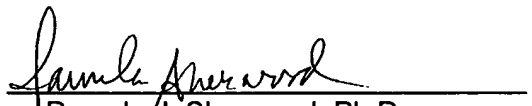
CONCLUSION

Applicant submits that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, she is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number STAN-541.

Respectfully submitted,

Date: January 24, 2007

By: 
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